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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/609,383	07/01/2003	Richard J. Feldmann		4498

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Richard J. Feldman
17800 Mill Creek Drive
Derwood, MD 20855-1019

EXAMINER

BRUSCA, JOHN S

ART UNIT	PAPER NUMBER
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1631

MAIL DATE	DELIVERY MODE
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10/30/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/609,383

Applicant(s)

FELDMANN, RICHARD J.

Examiner

John S. Brusca

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 3-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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DETAILED ACTION

1. Prosecution is reopened subsequent to the pre appeal brief review request filed 24 September 2008 to add a new grounds of rejection under 35 U.S.C. 101. As the application is now being prosecuted pro se by the applicant, the applicant is encouraged to contact the examiner at the phone number listed below should the applicant wish to discuss how to overcome the rejections of record. This Office action is a non-final Office action in view of the new grounds of rejection not necessitated by an applicant's amendment. The finality of the Office action mailed 28 May 2008 is **withdrawn**.

Status of the Claims

2. Claims 1-12 are pending.

Claims 3-12 are withdrawn

Claims 1 and 2 are rejected.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1 and 2 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1 and 2 are drawn to a process that includes embodiments that are entirely mental steps. The United States Court of Appeals for the Federal Circuit ruled in *In Re Stephen W.*

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Comiskey (84 USPQ2d 1670 (Fed. Cir. 2007)) that claimed subject matter drawn to mental steps were not eligible subject matter under 35 U.S.C. 101, and provided basis for the ruling as follows:

The Supreme Court has reviewed process patents reciting algorithms or abstract concepts in claims directed to industrial processes. In that context, the Supreme Court has held that a claim reciting an algorithm or abstract idea can state statutory subject matter only if, as employed in the process, it is embodied in, operates on, transforms, or otherwise involves another class of statutory subject matter, i.e., a machine, manufacture, or composition of matter. 35 U.S.C. §101. As the PTO notes, “[t]he Supreme Court has recognized only two instances in which such a method may qualify as a section 101 process: when the process ‘either [1] was tied to a particular apparatus or [2] operated to change materials to a ‘different state or thing.’” See PTO Supp. Br. 4 (quoting *Flook*, 437 U.S. at 588 n.9). In *Diehr*, the Supreme Court confirmed that a process claim reciting an algorithm could state statutory subject matter if it: (1) is tied to a machine or (2) creates or involves a composition of matter or manufacture.¹² 450 U.S. at 184. There, in the context of a process claim for curing rubber that recited an algorithm, the Court concluded that “[t]ransformation and reduction of an article ‘to a different state or thing’ is the clue to the patentability of a process claim that does not include particular machines.” *Id.* (quoting *Benson*, 409 U.S. at 70);¹³ see also *In re Schrader*, 22 F.3d 290, 295 [30 USPQ2d 1455] (Fed. Cir. 1994) (holding when a claim does not invoke a machine, “§101 requires some kind of transformation or reduction of subject matter”). Thus, a claim that involves both a mental process and one of the other categories of statutory subject matter (i.e., a machine, manufacture, or composition) may be patentable under §101. See *Diehr*, 450 U.S. at 184 (holding a process that involved calculations using the “Arrhenius equation” patentable because the claim “involve[d] the transformation of an article, in this case raw, uncured synthetic rubber, into a different state or thing”). For example, we have found processes involving mathematical algorithms used in computer technology patentable because they claimed practical applications and were tied to specific machines.¹⁴

¹² Of course, process claims not limited to claiming an abstract concept or algorithm (i.e., a mental process) may not be subject to the same requirements.

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¹³ See also *Diehr*, 450 U.S. at 184 (“*Industrial processes ... are the types which have historically been eligible to receive the protection of our patent laws.*” (emphasis added)); *Tilghman v. Proctor*, 102 U.S. 707, 722 (1880) (“A *manufacturing process* is clearly an art, within the meaning of the law.” (emphasis added)); *Cochrane v. Deener*, 94 U.S. 780, 788 (1876) (“A process is a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing.”).

¹⁴ See AT&T, 172 F.3d at 1355, 1358 (holding patentable “a process that uses the Boolean principle in order to determine the value of the PIC indicator” and that “require[d] the use of switches and computers”); *State Street Bank*, 149 F.3d at 1373 (“[W]e hold that the transformation of data ... by a *machine* through a series of mathematical calculations into a final share price, constitutes a *practical application* of a mathematical algorithm.” (emphases added)); *Alappat*, 33 F.3d at 1544 (“This is not a disembodied mathematical concept which may be characterized as an ‘abstract idea,’ but rather a specific *machine* to produce a *useful*, concrete, and tangible *result*.” (emphases added)); *Arrhythmia Research Tech., Inc. v. Corazonix Corp.*, 958 F.2d 1053, 1058-59 [22 USPQ2d 1033] (Fed. Cir. 1992) (holding patentable a method for analyzing electrocardiograph signals for the detection of a specific heart condition that used “electronic equipment programmed to perform mathematical computation”). However, mental processes—or processes of human thinking—standing alone are not patentable even if they have practical application. The Supreme Court has stated that “[p]henomena of nature, though just discovered, *mental processes*, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work.” *Benson*, 409 U.S. at 67 (emphasis added). In *Flook* the patentee argued that his claims did not seek to patent an abstract idea (an algorithm) because they were limited to a practical application of that idea—updating “alarm limits” for catalytic chemical conversion of hydrocarbons. 437 U.S. at 586, 589-90. The Court rejected the notion that mere recitation of a practical application of an abstract idea makes it patentable, concluding that “[a] competent draftsman could attach some form of post-solution activity to almost any mathematical formula.” *Id.* at 590. Since all other features of the process were well-known, including “the use of computers for ‘automatic monitoring-alarming,’” the Court construed the application as “simply provid[ing] a new and presumably better method for calculating alarm limit values.” *Id.* at 594-95. The Court held the application unpatentable because

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“if a claim [as a whole] is directed essentially to a method of calculating, using a mathematical formula, even if the solution is for a specific purpose, the claimed method is nonstatutory.” 437 U.S. at 595 (quoting *In re Richman*, 563 F.2d 1026, 1030 [195 USPQ 340] (CCPA 1977)).

Following the lead of the Supreme Court, this court and our predecessor court have refused to find processes patentable when they merely claimed a mental process standing alone and untied to another category of statutory subject matter even when a practical application was claimed. In *Schrader* we held unpatentable a “method constitut[ing] a novel way of conducting auctions” by allowing competitive bidding on a plurality of related items. 22 F.3d at 291. In doing so, we rejected the patentee’s argument that the process used a machine. Two of the alleged machines—a “display” in the front of the auction room and “a closed-circuit television system” for bidders in different cities—were not claimed by the patent, and the third—a “record” in which bids could be entered—could be “a piece of paper or a chalkboard.” *Id.* at 293-94. We therefore concluded that the patent impermissibly claimed unpatentable subject matter. Similarly, in *In re Warmerdam*, 33 F.3d 1354 [31 USPQ2d 1754] (Fed. Cir. 1994), we held unpatentable a process for controlling objects so as to avoid collisions because the key steps of “locating a medial axis” and “creating a bubble hierarchy” described “nothing more than the manipulation of basic mathematical constructs, the paradigmatic ‘abstract idea.’” *Id.* at 1360. A machine was not required, *id.* at 1358, nor was there any indication that the process operated on a manufacture or composition of matter.

Decisions of our predecessor court are in accord. *In re Meyer*, 688 F.2d 789, 796 [215 USPQ 193] (CCPA 1982), held that “a mental process that a neurologist should follow” was not patentable because it was “not limited to any otherwise statutory process, machine, manufacture, or composition of matter.” *Id.* at 795. Similarly, *In re Maucorps*, 609 F.2d 481 [203 USPQ 812] (CCPA 1979), held that an invention “[u]ltimately ... directed toward optimizing the organization of sales representatives in a business” was unpatentable. *Id.* at 482, 486. *See also Alappat*, 33 F.3d at 1541 (“*Maucorps* dealt with a business method for deciding how salesmen should best handle respective customers and *Meyer* involved a ‘system’ for aiding a neurologist in diagnosing patients. Clearly, neither of the alleged ‘inventions’ in those cases falls within any §101 category.”).¹⁵

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¹⁵ In *Musgrave*, our predecessor court concluded that the claims at issue in that case included non-mental steps and claimed patentable subject matter. 431 F.2d at 893. To the extent that language in the opinion might suggest that mental processes standing alone are patentable, the broad language in the opinion was significantly cabined by *Benson*. See 1 *Chisum on Patents* §1.03[6][c].

[2] It is thus clear that the present statute does not allow patents to be issued on particular business systems—such as a particular type of arbitration—that depend entirely on the use of mental processes. In other words, the patent statute does not allow patents on particular systems that depend for their operation on human intelligence alone, a field of endeavor that both the framers and Congress intended to be beyond the reach of patentable subject matter. Thus, it is established that the application of human intelligence to the solution of practical problems is not in and of itself patentable

To qualify as a statutory process, the claims should positively recite the other statutory class (the thing or product) to which it is tied, for example by identifying the apparatus that accomplishes the method steps, or positively recite the subject matter that is being transformed, for example by identifying the material that is being changed to a different state or thing. Nominal data gathering or post solution activity steps in the claimed subject matter will not be considered sufficient to convert a process that otherwise recites only mental steps into statutory subject matter. Preamble limitations that require the claimed process to comprise machine implemented steps will not be considered sufficient to convert a process that otherwise recites only mental steps into statutory subject matter. The applicants are cautioned against introduction of new matter in an amendment.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. For the purpose of examination the claims have been interpreted as requiring only computer-mediated sequence data analysis, without a requirement of physical manipulation of polynucleotides.
7. Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation." These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

In considering the factors for the instant claims:

a) Quantity of experimentation: The only utility asserted by the specification is to use connectron symmetries to predict control of gene expression (see for example pages 11, 15, and 16 of the specification). In order to practice the claimed invention one of skill in the art must identify and use a connectron to predict regulation of gene expression. In some embodiments

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changes in connectron behavior that correlate with changes in gene expression is monitored or effected. For the reasons discussed below, there would be an unpredictable amount of experimentation required to practice the claimed invention.

b) The amount of direction or guidance presented: The claimed invention is a method of identification of sequences that have a connectron relationship and act to modulate gene expression. On page 3, the specification defines connectrons as a tetradic structure between two sequences in an RNA transcript of a genomic sequence and two sequences in double stranded genomic DNA. The specification speculates without evidence on page 7 that triple-stranded (triplex) structures will form between RNA and double stranded DNA in chromatin where connectron symmetries of identical sequences are identified. The specification does not provide guidance that there are any limitations on formation of triplex structures, and only implies that regions of RNA with identical sequence to one strand of a double stranded DNA sequence will form triplex structures. The specification does not address why all RNA transcripts of genes which inherently have identical sequences would not form a continuous triplex structure with the gene from which it is transcribed. The specification provides guidance to identify connectron symmetries in genomic sequences. The specification does not provide detailed guidance to use identified connectron symmetries because the specification does not show whether or not connectrons form within cells or have an effect on gene expression. The specification does not provide specific guidance for monitoring or effecting changes in connectron behavior that correlate with gene expression.

c) The presence or absence of working examples: The specification provides working

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examples of identification of connectron symmetries by computer-mediated searching of genomic sequences. However, the specification does not provide evidence that connectron symmetries in genomic sequences result in formation of triplex RNA-DNA structures in which the RNA and DNA have identical sequences, or that if connectron triplex structures do exist that connectrons control gene expression. The specification does not provide working examples of using identified connectron symmetries to predict effects on gene expression. The specification does not provide working examples of monitoring or effecting changes in connectron behavior that correlate with gene expression.

d) The nature of the invention: The nature of the invention, gene expression control, is complex.

e) The state of the prior art: One of skill in the art, after reading the specification, would not know that connectron symmetries identified by computer-mediated searches of genomic sequences would allow for prediction of gene expression of genes that have connectron symmetries. The specification does not provide experimental evidence that connectron symmetries cause modulation of gene expression. Neither the prior art nor post-filing art shows connectrons. Mattick (published in 2001, one year after the effective instant filing date) reviews effects of RNA molecules on gene regulation. Mattick does not show connectrons as defined in the instant specification. Chan et al. reviews triplex DNA formation. Chan et al. shows in figures 1A-C that short stretches of oligonucleotides may form parallel or antiparallel triplex structures. Chan et al. shows in figures 1B that parallel triplex forming oligonucleotides form bonds between C and T residues of the oligonucleotide and G and A residues of the double stranded

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DNA molecule. Figure 1C shows that antiparallel triplex forming oligonucleotides form bonds between A, G, and T residues of the oligonucleotide and A, G, and A residues of the double stranded DNA. Chan et al. characterize the limited range of base pairing possibilities in triplex structures as pyrimidine binding motifs or purine binding motifs. Chan et al. describe on pages 268-273 the unpredictability and difficulty of forming desired triplex structures that are limited to the purine motif or the pyrimidine motif. Chan et al. does not show a mechanism that allows for triplex structures to form with regions of identical sequences between an RNA transcript and a region of double stranded DNA, as required for connectron formation as defined in the instant specification.

f) The relative skill of those in the art: The skill of those in the art of gene expression is high.

g) The predictability of the art: The predictability of the relationship of connectron symmetries and gene expression is unknown in the prior art and is not described in the instant specification.

h) The breadth of the claims: The claims are broad in that they are drawn to identification and modulation of connectron symmetries whose relationship to gene expression is not established.

The skilled practitioner would first turn to the instant specification for guidance in using the claimed invention. However, the specification lacks any evidence that connectrons form in cells or that connectron symmetries are related to gene expression. As such, the skilled practitioner would turn to the prior art for such guidance, however the prior art does not discuss

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connectron symmetries. Chan et al. shows that triplex formation occurs only with oligonucleotides with a purine rich or pyrimidine rich motif, rather than with any identical sequence as suggested in the specification. Finally, said practitioner would turn to trial and error experimentation to determine a relationship between connectron symmetries and gene expression. Such amounts to undue experimentation.

Response to Arguments

8. Applicant's arguments filed 27 March 2008 have been fully considered but they are not persuasive.

The applicants state that the reviews cited in the rejection are mere hearsay, however the reviews record the data and conclusions of other peer-reviewed academic papers and summarizes the state of the art as recognized by skilled practitioners in the art of molecular biology. As such the cited reviews Mattick and Chan et al. serve to establish what the prior art taught concerning the claimed subject matter. It is the combination of the teachings of the prior art and the teachings of the specification at the time of filing that must enable to make and use the claimed subject matter. For the reasons discussed above the rejection is maintained.

Conclusion

9. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR

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1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 571 272-0714. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie A. Moran can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John S. Brusca/

Primary Examiner

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jsb

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